What is claimed is:

1. An assay for detecting the presence of anti-HLA antibodies in a sample, the assay comprising:

   a substrate;

   a functionally active, individual soluble HLA molecule purified substantially away from other proteins such that the individual soluble HLA molecule maintains the physical, functional and antigenic integrity of the native HLA molecule, the functionally active, individual soluble HLA molecule directly or indirectly linked to the substrate; and

   means for detecting an anti-HLA antibody bound to the functionally active, individual soluble HLA molecule.

2. The assay of claim 1 wherein the substrate is a solid support.

3. The assay of claim 2 wherein the solid support is selected from the group consisting of a well, a bead, a membrane, an ELISA plate, a matrix, and combinations thereof.

4. The assay of claim 3 wherein the bead is selected from the group consisting of a flow cytometry bead, a Luminex bead, a Dynabead, a

magnetic bead and combinations thereof, and wherein the membrane is selected from the group consisting of a nitrocellulose membrane, a PVDF membrane, a nylon membrane, and acetate derivative, and combinations thereof.

5. The assay of claim 1 wherein the functionally active, individual soluble HLA molecule is indirectly attached to the substrate via an anchoring moiety.

6. The assay of claim 5 wherein the anchoring moeity comprises an antibody to the functionally active, individual soluble HLA molecule.

7. The assay of claim 6 wherein the antibody is selected from the group consisting of W6/32, anti-beta 2m, other Pan-Class I or allele-specific antibodies and combinations thereof.

8. The assay of claim 5 wherein the anchoring moiety comprises a tail or tag attached to the functionally active, individual soluble HLA molecule, and the substrate is further defined as comprising an affinity reagent to which the tail or tag binds.

9. The assay of claim 8 wherein the tail or tag is a histidine tag, and the affinity reagent is selected from the group consisting of nickel, copper and combinations thereof.

10. The assay of claim 8 wherein the tail or tag is a biotinylation signal peptide, and the affinity reagent is avidin or streptavidin.

11. The assay of claim 8 wherein the tail or tag is a VLDLr or FLAG tail, and the affinity reagent is an antibody that recognizes the VLDLr or FLAG tail.

12. The assay of claim 1 wherein the functionally active, individual soluble HLA molecule is a Class I HLA molecule or a Class II HLA molecule.

13. The assay of claim 1 wherein the functionally active, individual soluble HLA molecule is further defined as having an endogenous peptide loaded therein.

14. The assay of claim 1 wherein the functionally active, individual soluble HLA molecule is produced by a method comprising the steps of:

isolating HLA allele mRNA from a source and reverse transcribing the mRNA to obtain allelic cDNA;

amplifying the allelic cDNA by PCR, wherein the amplification utilizes at least one class I specific primer that truncates the allelic cDNA, thereby resulting in a truncated PCR product having the coding regions encoding cytoplasmic and transmembrane domains of the allelic cDNA removed such that the truncated PCR product has a coding region encoding a soluble HLA molecule;

inserting the truncated PCR product into a mammalian expression vector to form a plasmid containing the truncated PCR product having the coding region encoding a soluble HLA molecule;

electroporating the plasmid containing the truncated PCR product into at least one suitable host cell;

inoculating a cell pharm or a large scale mammalian tissue culture system with the at least one suitable host cell containing the plasmid containing the truncated PCR product such that the cell pharm produces soluble HLA molecules, wherein the soluble HLA molecules are folded naturally and are trafficked through the cell in such a way that they are identical in functional properties to an HLA molecule expressed from the HLA allele mRNA and

thereby bind peptide ligands in an identical manner as full-length, cell-surface-expressed HLA molecules;

harvesting the soluble HLA molecules from the cell pharm or large scale tissue culture system; and

purifying the individual, soluble HLA molecules substantially away from other proteins, wherein the individual soluble HLA molecules maintain the physical, functional and antigenic integrity of the native HLA molecule.

15. The assay of claim 14 wherein, in the step of isolating HLA allele mRNA from a source, the source is selected from the group consisting of mammalian DNA and an immortalized cell line.

16. The assay of claim 14 wherein, in the step of inserting the truncated PCR product into a mammalian expression vector, the mammalian expression vector contains a promoter that facilitates increased expression of the truncated PCR product.

17. The assay of claim 14 wherein, in the step of electroporating the plasmid containing the truncated PCR product into at least one suitable host cell, the suitable host cell lacks expression of Class I HLA molecules.

18. The assay of claim 14 wherein, in the step of amplifying the allelic cDNA by PCR, the class I specific primer includes a sequence encoding a tail such that the soluble HLA molecule encoded by the truncated PCR product contains a tail attached thereto that facilitates in purification of the soluble HLA molecules produced therefrom or facilitates in direct binding of the soluble HLA molecules to the substrate.

19. The assay of claim 14 wherein, in the step of amplifying the allelic cDNA by PCR, the at least one class I specific primer includes a stop codon incorporated into a 3' primer.

20. The assay of claim 14 wherein, in the step of purifying the individual, soluble HLA molecules substantially away from other proteins, the functionally active, individual soluble HLA molecule is purified by affinity chromatography and fractionation.

21. The assay of claim 20 wherein the affinity chromatography utilizes a reagent selected from the group consisting of W6/32 antibodies, anti-β2m antibodies, Pan-Class I antibodies or allele-specific antibodies, and combinations thereof.

22. The assay of claim 1 wherein the functionally active, individual soluble HLA molecule is produced by a method comprising the steps of:

obtaining gDNA encoding a HLA allele;

amplifying the allelic gDNA by PCR, wherein the amplification utilizes at least one class I specific primer that truncates the allelic gDNA, thereby resulting in a truncated PCR product having the coding regions encoding cytoplasmic and transmembrane domains of the allelic gDNA removed such that the truncated PCR product has a coding region encoding a soluble HLA molecule;

inserting the truncated PCR product into a mammalian expression vector to form a plasmid containing the truncated PCR product having the coding region encoding a soluble HLA molecule;

electroporating the plasmid containing the truncated PCR product into at least one suitable host cell;

inoculating a cell pharm with the at least one suitable host cell containing the plasmid containing the truncated PCR product such that the cell pharm produces soluble HLA molecules, wherein the soluble HLA molecules are folded naturally and are trafficked through the cell in such a way that they are identical in functional properties to an HLA molecule expressed from the HLA

allele mRNA and thereby bind peptide ligands in an identical manner as full-length, cell-surface-expressed HLA molecules;

harvesting the soluble HLA molecules from the cell pharm; and

purifying the individual, soluble HLA molecules substantially away from other proteins, wherein the individual soluble HLA molecules maintain the physical, functional and antigenic integrity of the native HLA molecule.

23. The assay of claim 22 wherein, in the step of obtaining gDNA which encodes a HLA allele, the gDNA is obtained from blood, saliva, hair, semen, or sweat.

24. The assay of claim 22 wherein, in the step of inserting the truncated PCR product into a mammalian expression vector, the mammalian expression vector contains a promoter that facilitates increased expression of the truncated PCR product.

25. The assay of claim 22 wherein, in the step of electroporating the plasmid containing the truncated PCR product into at least one suitable host cell, the suitable host cell lacks expression of Class I HLA molecules.

26. The assay of claim 22 wherein, in the step of amplifying the allelic cDNA by PCR, the class I specific primer includes a sequence encoding a tail such that the soluble HLA molecule encoded by the truncated PCR product contains a tail attached thereto that facilitates in purification of the soluble HLA molecules produced therefrom or facilitates in direct binding of the soluble HLA molecules to the substrate.

27. The assay of claim 22 wherein, in the step of amplifying the allelic cDNA by PCR, the at least one class I specific primer includes a stop codon incorporated into a 3' primer.

28. The assay of claim 22 wherein, in the step of purifying the individual, soluble HLA molecules substantially away from other proteins, the functionally active, individual soluble HLA molecule is purified by affinity chromatography and fractionation.

29. The assay of claim 28 wherein the affinity chromatography utilizes a reagent selected from the group consisting of W6/32 antibodies, anti-β2m antibodies, Pan-Class I or allele-specific antibodies, and combinations thereof.

30. The assay of claim 1 wherein the means for detecting an anti-HLA antibody is a labeled anti-human antibody recognizing human IgG, IgM or IgA antibodies.

31. A method for detecting the presence of anti-HLA antibodies in a sample, the method comprising the steps of:

providing a substrate having a functionally active, individual soluble HLA molecule linked thereto, the functionally active, individual soluble HLA molecule being purified substantially away from other proteins such that the individual soluble HLA molecule maintains the physical, functional and antigenic integrity of the native HLA molecule, the functionally active, individual soluble HLA molecule being directly or indirectly linked to the substrate;

providing a sample;

reacting the sample with the substrate having the functionally active, individual soluble HLA molecule linked thereto;

washing the substrate to remove unbound portions of the sample;

reacting the substrate having the functionally active, individual soluble HLA molecule linked thereto with means for detecting anti-HLA antibodies; and

determing that anti-HLA antibodies specific for the HLA molecule are present in the sample if the means for detecting anti-HLA antibodies is positive.

32. The method of claim 31 wherein, in the step of providing a substrate having a functionally active, individual soluble HLA molecule linked thereto, the substrate is a solid support.

33. The method of claim 32 wherein the solid support is selected from the group consisting of a well, a bead, a membrane, an ELISA plate, a matrix, and combinations thereof.

34.The method of claim 33 wherein the bead is selected from the group consisting of a flow cytometry bead, a Luminex bead, a Dynabead, a magnetic bead and combinations thereof, and wherein the membrane is selected from the group consisting of a nitrocellulose membrane, a PVDF membrane, a nylon membrane, and acetate derivative, and combinations thereof.

35. The method of claim 31 wherein, in the step of providing a substrate having a functionally active, individual soluble HLA molecule linked

thereto, the functionally active, individual soluble HLA molecule is indirectly attached to the substrate via an anchoring moiety.

36. The method of claim 35 wherein the anchoring moeity comprises an antibody to the functionally active, individual soluble HLA molecule.

37. The method of claim 36 wherein the antibody is selected from the group consisting of W6/32, anti-beta 2m, Pan-Class I or allele-specific antibodies and combinations thereof.

38. The method of claim 35 wherein the anchoring moiety comprises a tail or tag attached to the functionally active, individual soluble HLA molecule, and the substrate is further defined as comprising an affinity reagent to which the tail or tag binds.

39. The method of claim 38 wherein the tail or tag is a histidine tag, and the affinity reagent is selected from the group consisting of nickel, copper and combinations thereof.

40. The method of claim 38 wherein the tail or tag is a biotinylation signal peptide, and the affinity reagent is avidin or streptavidin.

41. The method of claim 38 wherein the tail or tag is a VLDLr or FLAG tail, and the affinity reagent is an antibody that recognizes the VLDLr or FLAG tail.

42. The method of claim 31 wherein, in the step of providing a substrate having a functionally active, individual soluble HLA molecule linked thereto, the functionally active, individual soluble HLA molecule is a Class I HLA molecule or a Class II HLA molecule.

43. The method of claim 31 wherein, in the step of providing a substrate having a functionally active, individual soluble HLA molecule linked thereto, the functionally active, individual soluble HLA molecule is further defined as having a natural mixture of endogenous peptides loaded therein.

44. The method of claim 31 wherein, in the step of providing a substrate having a functionally active, individual soluble HLA molecule linked thereto, the functionally active, individual soluble HLA molecule is produced by a method comprising the steps of:

isolating HLA allele mRNA from a source and reverse transcribing the mRNA to obtain allelic cDNA;

amplifying the allelic cDNA by PCR, wherein the amplification utilizes at least one class I specific primer that truncates the allelic cDNA, thereby resulting in a truncated PCR product having the coding regions encoding cytoplasmic and transmembrane domains of the allelic cDNA removed such that the truncated PCR product has a coding region encoding a soluble HLA molecule;

inserting the truncated PCR product into a mammalian expression vector to form a plasmid containing the truncated PCR product having the coding region encoding a soluble HLA molecule;

electroporating the plasmid containing the truncated PCR product into at least one suitable host cell;

inoculating a cell pharm or a large scale mammalian tissue culture system with the at least one suitable host cell containing the plasmid containing the truncated PCR product such that the cell pharm produces soluble HLA molecules, wherein the soluble HLA molecules are folded naturally and are trafficked through the cell in such a way that they are identical in functional properties to an HLA molecule expressed from the HLA allele mRNA and

thereby bind peptide ligands in an identical manner as full-length, cell-surface-expressed HLA molecules;

harvesting the soluble HLA molecules from the cell pharm or large scale tissue culture system; and

purifying the individual, soluble HLA molecules substantially away from other proteins, wherein the individual soluble HLA molecules maintain the physical, functional and antigenic integrity of the native HLA molecule.

45. The method of claim 44 wherein, in the step of isolating HLA allele mRNA from a source, the source is selected from the group consisting of mammalian DNA and an immortalized cell line.

46. The method of claim 44 wherein, in the step of inserting the truncated PCR product into a mammalian expression vector, the mammalian expression vector contains a promoter that facilitates increased expression of the truncated PCR product.

47. The method of claim 44 wherein, in the step of electroporating the plasmid containing the truncated PCR product into at least one suitable host cell, the suitable host cell lacks expression of Class I HLA molecules.

48. The method of claim 44 wherein, in the step of amplifying the allelic cDNA by PCR, the class I specific primer includes a sequence encoding a tail such that the soluble HLA molecule encoded by the truncated PCR product contains a tail attached thereto that facilitates in purification of the soluble HLA molecules produced therefrom or facilitates in direct binding of the soluble HLA molecules to the substrate.

49. The method of claim 44 wherein, in the step of amplifying the allelic cDNA by PCR, the at least one class I specific primer includes a stop codon incorporated into a 3' primer.

50. The method of claim 44 wherein, in the step of purifying the individual, soluble HLA molecules substantially away from other proteins, the functionally active, individual soluble HLA molecule is purified by affinity chromatography and fractionation.

51. The method of claim 50 wherein the affinity chromatography utilizes a reagent selected from the group consisting of W6/32 antibodies, anti-β2m antibodies, Pan-Class I antibodies or allele-specific antibodies, and combinations thereof.

52. The method of claim 31 wherein, in the step of providing a substrate having a functionally active, individual soluble HLA molecule linked thereto, the functionally active, individual soluble HLA molecule is produced by a method comprising the steps of:

obtaining gDNA encoding a HLA allele;

amplifying the allelic gDNA by PCR, wherein the amplification utilizes at least one class I specific primer that truncates the allelic gDNA, thereby resulting in a truncated PCR product having the coding regions encoding cytoplasmic and transmembrane domains of the allelic gDNA removed such that the truncated PCR product has a coding region encoding a soluble HLA molecule;

inserting the truncated PCR product into a mammalian expression vector to form a plasmid containing the truncated PCR product having the coding region encoding a soluble HLA molecule;

electroporating the plasmid containing the truncated PCR product into at least one suitable host cell;

inoculating a cell pharm with the at least one suitable host cell containing the plasmid containing the truncated PCR product such that the cell pharm produces soluble HLA molecules, wherein the soluble HLA molecules are folded naturally and are

trafficked through the cell in such a way that they are identical in functional properties to an HLA molecule expressed from the HLA allele mRNA and thereby bind peptide ligands in an identical manner as full-length, cell-surface-expressed HLA molecules;

harvesting the soluble HLA molecules from the cell pharm; and

purifying the individual, soluble HLA molecules substantially away from other proteins, wherein the individual soluble HLA molecules maintain the physical, functional and antigenic integrity of the native HLA molecule.

53. The method of claim 52 wherein, in the step of obtaining gDNA which encodes a HLA allele, the gDNA is obtained from blood, saliva, hair, semen, or sweat.

54. The method of claim 52 wherein, in the step of inserting the truncated PCR product into a mammalian expression vector, the mammalian expression vector contains a promoter that facilitates increased expression of the truncated PCR product.

55. The method of claim 52 wherein, in the step of electroporating the plasmid containing the truncated PCR product into at least one suitable host cell, the suitable host cell lacks expression of Class I HLA molecules.

56. The method of claim 52 wherein, in the step of amplifying the allelic cDNA by PCR, the class I specific primer includes a sequence encoding a tail such that the soluble HLA molecule encoded by the truncated PCR product contains a tail attached thereto that facilitates in purification of the soluble HLA molecules produced therefrom or facilitates in direct binding of the soluble HLA molecules to the substrate.

57. The method of claim 52 wherein, in the step of amplifying the allelic cDNA by PCR, the at least one class I specific primer includes a stop codon incorporated into a 3' primer.

58. The method of claim 52 wherein, in the step of purifying the individual, soluble HLA molecules substantially away from other proteins, the functionally active, individual soluble HLA molecule is purified by affinity chromatography and fractionation.

59. The method of claim 58 wherein the affinity chromatography utilizes a reagent selected from the group consisting of W6/32 antibodies, anti-β2m antibodies, Pan-Class I antibodies or allele-specific antibodies, and combinations thereof.

60.The method of claim 31 wherein, in the step of providing a sample, the sample is selected from the group consisting of serum, tissue, blood, cerobrospinal fluid, tears, saliva, lymph, dialysis fluid, organ or tissue culture derived fluids, fluids extracted from physiological tissues, and combinations thereof.

61.The method of claim 31 wherein, in the step of reacting the substrate having the functionally active, individual soluble HLA molecule linked thereto with means for detecting anti-HLA antibodies, the means for detecting anti-HLA antibodies is a labeled anti-human antibody recognizing human IgG, IgM or IgA antibodies.

62. A kit, comprising:

an assay for detecting the presence of anti-HLA antibodies in a sample, the assay comprising:

a substrate;

a functionally active, individual soluble HLA molecule purified substantially away from other proteins such that the individual soluble HLA molecule maintains the physical, functional and antigenic integrity of the native HLA molecule, the functionally active, individual soluble HLA molecule directly or indirectly linked to the substrate; and

means for detecting an anti-HLA antibody bound to the functionally active, individual soluble HLA molecule;

a positive control sample comprising anti-HLA antibodies that bind to the functionally active, individual soluble HLA molecule; and

a negative control sample wherein no anti-HLA antibodies that bind to the functionally active, individual soluble HLA molecule are present.

63. The kit of claim 62 wherein the substrate is a solid support.

64.The kit of claim 63 wherein the solid support is selected from the group consisting of a well, a bead, a membrane, an ELISA plate, a matrix, and combinations thereof.

65. The kit of claim 64 wherein the bead is selected from the group consisting of a flow cytometry bead, a Luminex bead, a Dynabead, a

magnetic bead and combinations thereof, and wherein the membrane is selected from the group consisting of a nitrocellulose membrane, a PVDF membrane, a nylon membrane, and acetate derivative, and combinations thereof.

66. The kit of claim 62 wherein the functionally active, individual soluble HLA molecule is indirectly attached to the substrate via an anchoring moiety.

67.The kit of claim 66 wherein the anchoring moeity comprises an antibody to the functionally active, individual soluble HLA molecule.

68.The kit of claim 67 wherein the antibody is selected from the group consisting of W6/32, anti-beta 2m, Pan-Class I or allele-specific antibodies and combinations thereof.

69.The kit of claim 66 wherein the anchoring moiety comprises a tail or tag attached to the functionally active, individual soluble HLA molecule, and the substrate is further defined as comprising an affinity reagent to which the tail or tag binds.

70.The kit of claim 69 wherein the tail or tag is a histidine tag, and the affinity reagent is selected from the group consisting of nickel, copper and combinations thereof.

71.The kit of claim 69 wherein the tail or tag is a biotinylation signal peptide, and the affinity reagent is avidin or streptavidin.

72. The kit of claim 69 wherein the tail or tag is a VLDLr or FLAG tail, and the affinity reagent is an antibody that recognizes the VLDLr or FLAG tail.

73. The kit of claim 62 wherein the functionally active, individual soluble HLA molecule is a Class I HLA molecule or a Class II HLA molecule.

74.The kit of claim 62 wherein the functionally active, individual soluble HLA molecule is further defined as having a natural mixture of endogenous peptides loaded therein.

75. The kit of claim 62 wherein the functionally active, individual soluble HLA molecule is produced by a method comprising the steps of:

isolating HLA allele mRNA from a source and reverse transcribing the mRNA to obtain allelic cDNA;

amplifying the allelic cDNA by PCR, wherein the amplification utilizes at least one class I specific primer that truncates the allelic cDNA, thereby resulting in a truncated PCR product having the coding regions encoding cytoplasmic and transmembrane domains of the allelic cDNA removed such that the truncated PCR product has a coding region encoding a soluble HLA molecule;

inserting the truncated PCR product into a mammalian expression vector to form a plasmid containing the truncated PCR product having the coding region encoding a soluble HLA molecule;

electroporating the plasmid containing the truncated PCR product into at least one suitable host cell;

inoculating a cell pharm or a large scale mammalian tissue culture system with the at least one suitable host cell containing the plasmid containing the truncated PCR product such that the cell pharm produces soluble HLA molecules, wherein the soluble HLA molecules are folded naturally and are trafficked through the cell in such a way that they are identical in functional properties to an HLA molecule expressed from the HLA allele mRNA and

thereby bind peptide ligands in an identical manner as full-length, cell-surface-expressed HLA molecules;

harvesting the soluble HLA molecules from the cell pharm or large scale tissue culture system; and

purifying the individual, soluble HLA molecules substantially away from other proteins, wherein the individual soluble HLA molecules maintain the physical, functional and antigenic integrity of the native HLA molecule.

76. The kit of claim 75 wherein, in the step of isolating HLA allele mRNA from a source, the source is selected from the group consisting of mammalian DNA and an immortalized cell line.

77. The kit of claim 75 wherein, in the step of inserting the truncated PCR product into a mammalian expression vector, the mammalian expression vector contains a promoter that facilitates increased expression of the truncated PCR product.

78. The kit of claim 75 wherein, in the step of electroporating the plasmid containing the truncated PCR product into at least one suitable host cell, the suitable host cell lacks expression of Class I HLA molecules.

79. The kit of claim 75 wherein, in the step of amplifying the allelic cDNA by PCR, the class I specific primer includes a sequence encoding a tail such that the soluble HLA molecule encoded by the truncated PCR product contains a tail attached thereto that facilitates in purification of the soluble HLA molecules produced therefrom or facilitates in direct binding of the soluble HLA molecules to the substrate.

80. The kit of claim 75 wherein, in the step of amplifying the allelic cDNA by PCR, the at least one class I specific primer includes a stop codon incorporated into a 3' primer.

81. The kit of claim 75 wherein, in the step of purifying the individual, soluble HLA molecules substantially away from other proteins, the functionally active, individual soluble HLA molecule is purified by affinity chromatography and fractionation.

82. The kit of claim 81 wherein the affinity chromatography utilizes a reagent selected from the group consisting of W6/32 antibodies, anti-β2m antibodies, Pan-Class I antibodies or allele-specific antibodies, and combinations thereof.

83. The kit of claim 62 wherein the functionally active, individual soluble HLA molecule is produced by a method comprising the steps of:

obtaining gDNA encoding a HLA allele;

amplifying the allelic gDNA by PCR, wherein the amplification utilizes at least one class I specific primer that truncates the allelic gDNA, thereby resulting in a truncated PCR product having the coding regions encoding cytoplasmic and transmembrane domains of the allelic gDNA removed such that the truncated PCR product has a coding region encoding a soluble HLA molecule;

inserting the truncated PCR product into a mammalian expression vector to form a plasmid containing the truncated PCR product having the coding region encoding a soluble HLA molecule;

electroporating the plasmid containing the truncated PCR product into at least one suitable host cell;

inoculating a cell pharm with the at least one suitable host cell containing the plasmid containing the truncated PCR product such that the cell pharm produces soluble HLA molecules, wherein the soluble HLA molecules are folded naturally and are trafficked through the cell in such a way that they are identical in functional properties to an HLA molecule expressed from the HLA

allele mRNA and thereby bind peptide ligands in an identical manner as full-length, cell-surface-expressed HLA molecules;

harvesting the soluble HLA molecules from the cell pharm; and

purifying the individual, soluble HLA molecules substantially away from other proteins, wherein the individual soluble HLA molecules maintain the physical, functional and antigenic integrity of the native HLA molecule.

84. The kit of claim 83 wherein, in the step of obtaining gDNA which encodes a HLA allele, the gDNA is obtained from blood, saliva, hair, semen, or sweat.

85. The kit of claim 83 wherein, in the step of inserting the truncated PCR product into a mammalian expression vector, the mammalian expression vector contains a promoter that facilitates increased expression of the truncated PCR product.

86. The kit of claim 83 wherein, in the step of electroporating the plasmid containing the truncated PCR product into at least one suitable host cell, the suitable host cell lacks expression of Class I HLA molecules.

87. The kit of claim 83 wherein, in the step of amplifying the allelic cDNA by PCR, the class I specific primer includes a sequence encoding a tail such that the soluble HLA molecule encoded by the truncated PCR product contains a tail attached thereto that facilitates in purification of the soluble HLA molecules produced therefrom or facilitates in direct binding of the soluble HLA molecules to the substrate.

88. The kit of claim 83 wherein, in the step of amplifying the allelic cDNA by PCR, the at least one class I specific primer includes a stop codon incorporated into a 3' primer.

89. The kit of claim 83 wherein, in the step of purifying the individual, soluble HLA molecules substantially away from other proteins, the functionally active, individual soluble HLA molecule is purified by affinity chromatography and fractionation.

90. The kit of claim 89 wherein the affinity chromatography utilizes a reagent selected from the group consisting of W6/32 antibodies, anti-β2m antibodies, Pan-Class I antibodies or allele-specific antibodies, and combinations thereof.

91.The kit of claim 62 wherein the means for detecting an anti-HLA antibody is a labeled anti-human antibody recognizing human IgG, IgM or IgA antibodies.

92. A kit, comprising:

an assay for detecting the presence of anti-HLA antibodies in a sample, the assay comprising:

a substrate;

a functionally active, individual soluble HLA molecule purified substantially away from other proteins such that the individual soluble HLA molecule maintains the physical, functional and antigenic integrity of the native HLA molecule, the functionally active, individual soluble HLA molecule directly or indirectly linked to the substrate; and

means for detecting an anti-HLA antibody bound to the functionally active, individual soluble HLA molecule; and

at least one control sample selected from the group consisting of a positive control sample comprising anti-HLA antibodies that bind to the functionally active, individual soluble HLA molecule, a negative control sample wherein no anti-HLA antibodies that bind

to the functionally active, individual soluble HLA molecule are present, and combinations thereof.